

From: Joseph Schulman

To: John Kennedy

Date: December 03, 2004

Subject:

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Message:

The Alfred Mann Foundation (AMF) does not have any contractual arrangements with the participants in the studies. AMF also does not have any financial arrangements with the participants requiring them to pay AMF for the equipment or for participating in the studies. The hospitals and other medical centers where these studies are conducted, however, are permitted by law to charge the participants, provided that the amount charged is less than the research and development (R&D) costs. Participants in the feasibility studies typically are not charged any fees for the equipment, but those in the pivotal studies may be charged a fee by the medical center to recoup its R&D costs. AMF does not receive these fees from either the medical center or the participant.